

REMARKS

Claims 1, 4, 5-6, 9-11, 13, 15, 17, and 19 remain in this application. Claims 1, 4 and 9-11 are amended. Claims 2-3, 7-8, 12, 14, 16, 18, and 20 are canceled. Support for the amendments to claim 1 may be found, for example, on page 7, Table I, last row. Claim 4 is amended merely to clarify the meaning of "compound comprising MSM," in view of the rejection under 35 U.S.C. § 112. Claims 9-11 are amended for consistency with the amendments to claim 1 and to avoid depending from a canceled claim. By these amendments, no new matter has been added.

Applicant thanks the Examiner for her patience and suggestions during the interview with applicant on July 28, 2009.

Claims 4-5 stand rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Without making any concession as to definiteness of the claim 4 prior to the present amendments, claim 4 has been amended to define "delivering the effective amount of methyl sulfonyl methane by periodically ingesting in a compound comprising methyl sulfonyl methane and other ingredients." Claim 4 as amended has a clear and definite meaning, defining that the "compound" comprises MSM and other ingredients, and therefore does not define a double dose of MSM. Therefore, these rejections should be withdrawn.

Claims 1, 2, 4, 18 and 19 stand rejected under 35 U.S.C. § 102(b) as anticipated by Herschler (US 4863748). These rejections are respectfully traversed. Herschler fails to disclose or suggest the element of **"delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step,"** as defined by claim 1. As acknowledged in the office action, none of the references, including Herschler, recognize any usefulness for MSM in lightening of skin tone. Nor is it true that noticeable skin lightening would inherently – that is, necessarily – occur using any of the

topical or oral administrations taught by Herschler. As demonstrated by the examples in the present application, MSM may, or may not, cause noticeable skin lightening, depending on the dose, route of administration, and duration of administration. See Table 3.

Herschler discloses orally administering 250-500 mg of MSM for up to one year (Example 12). Based on this disclosure, the Office Action asserts that Herschler discloses administering an effective amount of MSM for skin lightening. This is not correct. To the contrary, as shown in Table 3 of the present application, at least 2000 mg/day is needed for a 45 kg adult female. Herschler therefore fails to disclose administering an effective amount of MSM to cause noticeable skin lightening.

In addition, Herschler also fails to disclose **"wherein the effective amount comprises orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months,"** as also defined by claim 1. The maximum dose suggested by Herschler is 500 mg, which even in a small (45 kg) adult is substantially less than the recited 133 mg/kg/day. Herschler therefore also cannot anticipate this element.

In view of the deficiencies of Herschler outlined above, it cannot anticipate claim 1, which is therefore allowable. Claims 4 and 19 are also allowable, at least as depending from an allowable base claim. Claims 2 and 18 are canceled. These rejections should therefore be withdrawn.

Claims 3, 5-7, 9-12, 17 and 20 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Herschler and Petrus (US 6573299). These rejections are respectfully traversed.

As noted above, Herschler fails to disclose **"delivering an effective amount of methyl sulfonyl methane to a person for developing a lighter skin tone by ingestion of the effective amount, at least until the person develops a skin tone noticeably lighter than before commencement of the delivery step,"** and **"wherein the effective amount comprises orally administered doses in an amount of at**

least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months," as defined by claim 1.

Petrus does not make up for these deficiencies. At column 11, lines 60-65, Petrus discloses "the therapeutic dosage range for MSM is 2-10 grams orally per day," and "[t]he recommended topical dosage range of the present invention is 1-5 grams. Petrus fails to teach any specific period of time for the "therapeutic dosage range" or for the "recommended topical dosage range." Petrus also fails to disclose any oral or topical dose per unit of body weight. Since Petrus does not teach any particular body weight for the range, it is not possible to equate this to a per-kilogram minimum dose, as claimed. Moreover, Petrus is concerned only with **topical** application of MSM for the "present invention," and teaches nothing about the oral dose of 2-10 grams other than noting it is "therapeutic." Petrus does not disclose what therapeutic uses the oral dose of MSM would have been used for, or any other details of dosing for such therapeutic uses. There is nothing in Petrus or Hershler that teaches the claimed specific minimum dosing regimen of **"orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months."**

The examiner also states that since Herschler "teaches that MSM improves the complexion of skin, one of ordinary skill in the art would obviously have observed and/or expected that MSM changes skin color tone after the MSM treatment." Office action, p. 4. This statement is incorrect, because there is no known link between skin color tone and complexion -- one would not expect an acne treatment to change color tone. Moreover, Hershler fails to teach a dosage regimen that would actually have caused skin lightening, so in fact one of ordinary skill would have observed no skin lightening by following the regimen disclosed by Herschler. There is no reason apparent in the record why one of ordinary skill would have proscribed **"orally administered doses in an amount of at least 133 mg of methyl sulfonyl methane per kilogram of body weight per day continuing for not less than three months."** The claimed regimen

clearly exceeds the 500 mg dose taught by Herschler, while also being specific as to body weight and period, which Herschler fails to disclose. For its part, Petrus teaches topical administration of MSM and only makes only a very brief passing reference to therapeutic uses of MSM, consisting of one sentence in total. Petrus utterly lacks any details concerning oral administration of MSM, except for its one sentence mentioning a range of 2-10 grams, with no further details. Taken together, and separately, Petrus and Herschler fail to teach all elements defined by claim 1.

As shown above, Herschler and Petrus, both separately and in combination, fail to disclose all of the elements of independent claim 1. Claims 5-6, 9-11 and 17 are also allowable, at least as depending from an allowable base claim. Claims 3, 7, 12, and 20 have been canceled. These rejections should therefore be withdrawn.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as unpatentable over Herschler, Petrus and Kirby (US 6444234). Claim 8 has been canceled, and this rejection is therefore moot, and should be withdrawn.

Claims 13-16 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Herschler, Petrus, and Flick (Cosmetic and Toiletry Formulations, vol. 6.) Flick merely discloses use of an exfoliate, and fails to make up for the deficiencies of Herschler and Petrus noted above. Claims 13 and 15 are therefore allowable, at least as depending from an allowable base claim. Claims 14 and 16 have been canceled. These rejections should therefore be withdrawn.

* * *

In view of the foregoing, the Applicant respectfully submits that claims 1, 4, 5-6, 9-11, 13, 15, 17, and 19 are in condition for allowance. Reconsideration and withdrawal of the rejections is respectfully requested, and a timely Notice of Allowability is solicited.

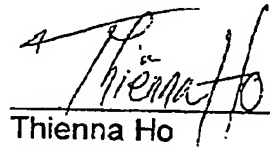
The arguments presented herein are sufficient to fully traverse the rejections set forth in the Office Action. Therefore, Applicant has not presented all possible arguments, and may not have refuted the characterizations of either the claims or the prior art as may be found in the record. However, the lack of such arguments or

Serial No. 10/559,779
August 11, 2009
Page 9

refutations is not intended to waive such arguments or indicate concurrence with such characterizations.

Respectfully submitted,

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